Message

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To: OPP HED [OPP_HED@epa.gov]
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Attachments: HED Weekly 8-28-20 final.docx

HED NEWS

Week Ending
8/28/2020

For the Office Director

**** SENSITIVE – NOT FOR DISTRIBUTION ****

Conference Call with Syngenta Regarding Chlorothalonil Study Submissions
Staff from HED (Monique Perron) and PRD held a conference call with a representative from Syngenta to discuss the status *in vitro* repeat dosing studies being performed for chlorothalonil to address comments from the Scientific Advisory Panel (SAP) on the proposed approach for inhalation risk assessment refinements for contact irritants. Syngenta indicated that the study reports have been completed and will be submitted to EPA as soon as possible. An associated report with benchmark dose (BMD) analyses is almost complete and should be submitted in the near future. New computational fluid dynamic (CFD) modeling was also completed to address SAP comments, but Syngenta indicated reports will not be completed until mid-September. (Monique Perron; 703-347-0395)

Conference Call on Buprofezin Label Revision for Registration Review Risk Mitigation. Members of HED and PRD participated in a conference call with the registrant for buprofezin to discuss label revisions required under the Buprofezin Interim Decision (ID) to specify application rates for indoor fogging of greenhouses. The registrant presented information regarding fogging equipment permitted on the label. New information regarding the dilution rate for fogging equipment in greenhouses in terms of gallons applied to a defined area which were provided after the DRA was completed were discussed. This new information will be considered in conjunction with the ID requirements. (Brian Van Deusen, 703-347-8025)

Meeting with Registrant Regarding Pre-submission Data on Human Relevance of Liver Tumor in Mice with S-3100 Based on Mode of Action.
Staff from HED and RD held a conference call meeting with representatives from Sumitomo Chemical, Valent, Bayer, and Canada's PMRA on August 24, 2020 to discuss pre-submission data for S-3100. Data on the human relevance of a proposed mode of action (MOA) for liver tumors in mice were presented. The final submission is expected in November 2021 (Yung Yang, 703-308-2721)

Pre-Interim Decision Meeting with FMC Corporation and Syngenta for Lambda- and Gamma-Cyhalothrin. The HED/RAB VI lambda- and gamma-cyhalothrin team along with EFED, BEAD, and PRD attended a pre-interim decision (PID) teleconference with FMC Corporation on August 20th and Syngenta on August 21st to discuss PRD's proposed mitigation for lambda- and gamma-cyhalothrin as part of Registration Review. PRD briefly summarized the risks of concern identified in the human health and ecological risk assessments, discussed how registrant comments impacted the risk assessments, and presented EPA's mitigation strategy. EPA provided feedback on comments from the registrant. The registrants will continue to work with PRD to further support and characterize the mitigation presented in the PID discussion. The risk assessment team included Tom Bloem, Yung Yang, and Monica Hawkins. (Monica Hawkins, 703-305-6459)

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September 2020 Scientific Advisory Panel Preparatory Meeting
Staff from OPP-HED and ORD participated in a public preparatory meeting for the upcoming Scientific Advisory Panel (SAP) meeting that will take place September 15-18, 2020. The SAP will be considering information on two applications of new approach methodologies (NAMs). Monique Perron (HED) presented an overview of the NAMs and the current SAP charge questions. HED and ORD provided clarifications to panel members on the charge questions and will revise them accordingly based on the discussion. (Monique Perron; 703-347-0395)

Chemical	Deliverable	Branch
Difenoconazole	Human Health Risk Assessment	RAB IV

For HED

RAB IV Completed the Draft Human Health Risk Assessment for Difenoconazole. RAB IV completed the draft human health risk assessment (DRA) to support registration review for difenoconazole. The hazard characterization, as well as, the dietary, residential, aggregate, and occupational risk assessments for difenoconazole were updated for the DRA. A quantitative spray drift assessment was also conducted. Updates to the hazard characterization included removal of dermal endpoints and higher points of departure (compared to previous risk assessment) for all other endpoints, with the exception of the acute dietary endpoint. There were no risk estimates of concern identified in the assessment. The RAB IV risk assessment team included: Bonnie Cropp-Kohlligian, Minerva Mercado-Feliciano, Thurston Morton, and Carolyn Mottley. (Bonnie Cropp-Kohlligian, 703-305-7462)

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